

**REMARKS**

Claims 1 to 16, 28 to 36, and 61 to 64 are pending, and claims 1 to 15, 36, 61, and 62 have been withdrawn from consideration. Claims 16, 28 to 35, 63, and 64 are under examination.

The Examiner has rejected claim 16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,046 to Passafaro et al. (Passafaro). Applicant respectfully traverses this rejection.

Claim 16 is directed to a device for removing material from a vessel wall at a vascular site and comprises both an expandable cage and a material removing element positioned within a cavity defined by an inner surface of the cage. The Examiner states that Passafaro discloses a stent having the features of the cage recited in claim 16 and a material removal element 54 positioned within the cage cavity. Therefore, the Examiner concludes that Passafaro anticipates claim 16. Applicant respectfully points out, however, that the stent forms no part of the system disclosed by Passafaro.

Specifically, Passafaro discloses a system 30 that includes a catheter 32 which has a flexible elongate catheter body 34 having a proximal end 36 and a distal end 38, and defining at least one lumen 50 extending longitudinally therethrough. The catheter is coupled to a hand-held device 42 and a collection reservoir 44. The hand-held device includes a motor for rotating a removal mechanism 54 provided at a distal end 38 of the catheter 32 to extract occluding material. (Passafaro, col. 8, lines 15 to 25). The system disclosed by Passafaro is for removing stenotic material from blood vessels including vessels in which a stent has been previously implanted. (Passafaro, col. 7, lines 18 to 21 and col. 20, lines 1 to 3 and lines 7 to 13). In other words, the system which is disclosed by Passafaro does not include the stent which is described as having been previously implanted.

In order to anticipate under 35 U.S.C. § 102 a prior art reference must not only disclose all of the elements of the claim within the four corners of the document but must also disclose those elements “arranged as in the claim”. *Net Moneyin v. Versign*, 545 F. 3d 1359, 1369 (Fed. Cir. 2008). In making this rejection the Examiner has combined an element of the removal device disclosed by Passafaro with an element that Passafaro clearly discloses as being an element (the stent) of a different device which was previously implanted in a different and prior procedure. Clearly, Passafaro does not disclose the elements of claim 16, as arranged in the claim, which requires a device that includes both a cage and a material removal element. Therefore, Passafaro does not anticipate claim 16 and Applicant respectfully requests that the Examiner withdraw this rejection.

The Examiner has rejected claims 63 and 64 under U.S.C. § 103(a) as being unpatentable over Passafaro in view of U.S. Patent No. 5,211,651 to Reger et al. (Reger). Applicant respectfully traverses this rejection. Claims 63 and 64 depend from claim 16 and add further significant limitations. Claim 16 is allowable over Passafaro for at least the reasons set forth above. Reger does not disclose or teach a device having the features of claim 16 and, therefore, does not overcome the deficiencies of Passafaro. Therefore, claims 63 and 64 are allowable for at least the same reasons as claim 16.

The Examiner has rejected claims 28 to 30 and 33 under U.S.C. § 103(a) as being unpatentable over Passafaro in view of U.S. Patent No. 5,776,141 to Klein et al. (Klein). Applicant believes the Examiner has also rejected claims 34 and 35 for the same reasons. Applicant respectfully traverses this rejection.

Claim 28 is directed to a device for removing material from a vessel wall at a vascular site and comprises a sheath, an expandable cage and a material removing element positioned within a cavity defined by an inner surface of the cage. The sheath is retractable relative to the cage to expose the cage and permit the cage to expand. As

discussed above, Passafaro does not disclose a device which includes an expandable cage and a material removal element. The cage referred to by the Examiner in the rejection is a stent which was part of a different treatment system or device and which was previously implanted and left in the vessel during a different treatment procedure.

Applicant submits that a person of skill in the art would not, in view of the combined teaching of Passafaro and Klein, modify the material removal device disclosed in Passafaro to include a stent, considered by the Examiner to comprise a cage. The device disclosed by Passafaro is intended to be used to remove occluding material from a body vessel, including occluding material from within a stent which was previously implanted in the vessel. The stent, however, plays no part in the material removal process. As a matter of fact, the stent complicates the process. As stated by Passafaro, “[t]reatment of an occluded stent faces all the difficulties discussed above with respect to treatment of initial occlusions and is further complicated by the need to avoid damaging the stent during the removal of the hyperplasia occluding material.” (Passafaro, col. 2, lines 58 to 63). Therefore, a person of skill in the art would have no reason to intentionally incorporate a stent into the device disclosed by Passafaro (or a stent and sheath as disclosed in Klein) since such modification would provide no functional advantage and would, in fact, further complicate use of the device. For at least these reasons Applicant believes claim 28 is allowable and request that the Examiner withdraw the rejection.

Claims 29, 30, 33, 34 and 35 depend from claim 28 and add further significant limitations. Therefore, claims 29, 30, 33, 34 and 35 are allowable for at least the same reasons as claim 28.

The Examiner has rejected claims 31 and 32 under U.S.C. § 103(a) as being unpatentable over Passafaro in view of Klein and further in view of Reger. Applicant respectfully traverses this rejection. Claims 31 and 32 depend from claim 28 and add

further significant limitations. Reger does not disclose or teach a device having the features of claim 28 and, therefore, does not overcome the deficiencies of Passafaro and Klein. Therefore, claims 31 and 32 are allowable for at least the same reasons as claim 28.

In view of the foregoing Applicant submits that all of the pending claims are allowable and requests that the rejections be withdrawn.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

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